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Docket No. 98N-1215

Comments on the proposed rule – Foreign Establishment Registration and Listing

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Submitted by:

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I. Preamble Section C: Proposed Changes to Part 807 (Devices), Comment 1(b) – Definition of "United States agent," appearing on page 26336

This definition must include the same language used in explaining the definition of United States agent in Section 207.3, which appears on page 26331. This way there is no misunderstanding about the need for the U.S. Agent to have a physical place of business versus just a post office box. Specifically, the following language should replace the existing information in the preamble for Part 807.3(r):

> b. Definition of ``United States agent''. Currently, Sec. 807.3(r) defines a ``U.S.-designated agent'' as a person, residing in the United States, who is ``designated and authorized by the owner or operator of a foreign manufacturer who exports devices into the United States'' and who is responsible for submitting medical device reports and annual certifications, acting as the official correspondent, and submitting registration and listing information and premarket notifications. In the Federal Register of July 23, 1996 (61 FR 38345), FDA stayed the effective date for this and other provisions in part 807 (and elsewhere) that mention a U.S.-designated agent.
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> The proposed rule would revise Sec. 807.3(r) to define a ``United States agent'' as ``a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent.'' Black's Law Dictionary defines ``reside'' as ``live, dwell, abide, sojourn, stay, remain, lodge'' and ``to settle oneself or a thing in a place, to be stationed, to remain or stay, to dwell permanently or continuously * * *'' (see Black's Law Dictionary 1308 (6th ed. 1990)) and defines ``place of business,'' in part, as ``The location at which one carries on his business or employment'' (id. at 1149). Thus, by using the term ``residing'' and referring to a ``place of business,'' proposed Sec. 807.3(r) would permit a foreign establishment to designate, as its United States agent, either an individual who lives in the United States or a firm or company in the United States where an individual or individuals conduct business or are employed. The

98N-1215

C 16

definition of United States agent would exclude mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present. As stated earlier, FDA interprets the statutory requirement of a United States agent as allowing for only one United States agent for each foreign establishment and providing a foreign establishment the discretion to choose either an individual person or entity to serve as its United States agent.

Additionally, unlike the existing provision, proposed Sec. 807.3(r) would not prescribe any duties for the United States agent. Proposed Sec. 807.40 would describe the United States agent's responsibilities and is discussed later in this document.

II. Need to amend 807.65 – Exemptions for device establishments

This section needs to be amended just like 207.10 and 607.65. The amendment needs to eliminate the exemptions for foreign establishments or foreign persons listed in 807.65(d), (e), (f) and (i).

Respectfully submitted by Bryan H. Benesch, July 28, 1999